

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
74-R-0106

CUSTOMER NO.  
9464

FORM APPROVED  
OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

AMERICAN ANIMAL HEALTH, INC.  
2619 SKYWAY DRIVE  
GRAND PRAIRIE, TX 75052  
(972) 641-5420

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

## FACILITY LOCATIONS(sites)

See Attached Listing

See Attachment #1

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS  (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Cattle	0	20	0	149	169
13. Other Animals					
goat	0	0	425	0	425

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

OCT - 2 2007

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

IAL OFFICIAL (Type or Print)

DATE SIGNED

10/1/07

(b)(6), (b)(7)c

PART 1 - HEADQUARTERS

9.

Goats

10.

Goats

(b)(2)High, (b)(7)f

11.

Cattle

12.

Cattle

## Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 74-R-0106
2. Number 169 of animals used in this study.
3. Species (common name) Cattle of animals used in the study.

4. Explain the procedure producing pain and/or distress.

The animals were used in the challenge protection tests conducted to demonstrate host animal immunogenicity for the licensing application of *Mycobacterium bovis* Bacterin, Code 2760.01 and *Pasteurella haemolytica*-*Pasteurella multocida* Bacterin Toxoid, Codes # 7935.02 and # 7935.03. Out of the 169 animals used in the test, 20 were used as environmental controls that they were not challenged, however, they were also sacrificed to see effect of the environment. The other 149 animals were used either as vaccinates or placebo. They were all challenged 21 days post vaccination, if Code 2760.01 and Code 7935.03. These animals used in the Code 7935.02 were receiving two vaccinations and challenged 42 days later after 2nd vaccination. Since the USDA requires observation for clinical signs postchallenge, we are sure that this requirement would produce some degree of pain and distress for animals depending on the degree of protection. For these placebo, approximately 33 animals were suffered through out the challenge period of time.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The above-mentioned host animal immunogenicity work involved pneumonia protection. Although the pivotal analysis were based on lung lesion scores. The USDA requires whether products help mitigating clinical signs. Therefore, pain and/or distress could not be relieved.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency USDA Vet. Service Memorandum No. 800.202  
-CFR General Licensing Consideration: Efficacy Studies.

OCT - 2 2007